UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *et al.*, Plaintiffs and Relator, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	11 Civ. 0071 (PGG)
UNITED STATES OF AMERICA, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	

JOINT PRETRIAL ORDER

The parties having conferred among themselves pursuant to Fed. R. Civ. P. 16, the following statements, directions, and agreements are adopted as the Pretrial Order herein.

I. FULL CAPTION OF THE ACTION

The full caption of the action appears above.

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III. SUBJECT MATTER JURISDICTION

The United States brings its claims pursuant to the False Claims Act, 31 U.S.C. § 3729 (the "FCA"). The parties agree that this court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1345,

and 31 U.S.C. § 3730(a). The Court has supplemental jurisdiction over the counts relating to the state False Claims Acts and New York state causes of action pursuant to 28 U.S.C. § 1367.

IV. SUMMARIES OF CLAIMS AND DEFENSES

A. Plaintiffs' Summary of Claims

The United States brings two claims against Novartis Pharmaceuticals Corporation pursuant to the federal False Claims Act. First, the United States alleges that Novartis violated the federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A), by knowingly causing false or fraudulent claims to be submitted to Medicare, Medicaid, and TRICARE (collectively, government health insurance programs). Specifically, the United States alleges that Novartis offered illegal bribes to health care practitioners to induce them to prescribe Diovan, Diovan HCT, Exforge, Exforge HCT, Lotrel, Starlix, Tekturna, Tekturna HCT, Tekamlo, and Valturna, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(g). The United States further alleges that these illegal bribes rendered claims for reimbursement for prescriptions for those drugs from federal health insurance programs false or fraudulent. Second, the United States alleges that Novartis violated the federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B), by causing false statements material to a false or fraudulent claim to be made or used. Specifically, the United States alleges that Novartis caused the submission of false certifications, statements, or attestations regarding compliance with either the Anti-Kickback Statute specifically, or applicable state or federal law generally, to government health insurance programs.

The United States also asserts a common law claim against Novartis for unjust enrichment. Specifically, the United States alleges that, through the Government Health Insurance Programs, it conferred a benefit on Novartis in the form of reimbursements for Novartis drugs, that Novartis retained that benefit, and that under the circumstances—namely, Novartis having provided illegal bribes to doctors to prescribe such drugs—it would be unjust for Novartis to retain that benefit.

Relator and the State of New York bring analogous claims pursuant to identical provisions of state False Claims Act provisions to recover the state share of moneys paid out for false or fraudulent claims submitted to state Medicaid programs.

In addition to claims brought under its state False Claims Act, the State of New York ("New York") brings two additional claims against Novartis under New York statutory and common law causes of action. First,, New York brings a claim against Novartis pursuant to New York Executive Law Sec. 63-c, which allows New York to recover funds or demand compensation from individuals or entities who obtain funds belonging to New York without right. New York alleges that, by engaging in the conduct described above, Novartis obtained funds from the New York Medicaid program without right, and seeks restitution in the amount of its overpayment of Medicaid funds resulting from Novartis' conduct. Second, New York brings a common law claim for unjust enrichment against Novartis, and seeks repayment of monies wrongly obtained by Novartis as a result of Novartis's conduct described above.

B. Defendant's Summary of Defenses

Novartis denies that it violated the Anti-Kickback Statute ("AKS"), the federal and state False Claims Acts ("FCA"), or any other federal or state law. Novartis denies that it offered, or intended to offer, bribes to health care practitioners and contends that it conducted legitimate and lawful promotional programs.

The Plaintiffs cannot prove their alleged case at trial. Novartis's challenged conduct did not involve "illegal remuneration" nor did Novartis have the necessary mens rea to violate the AKS or FCA. The Plaintiffs also cannot show that the challenged prescriptions were induced by alleged kickbacks. Indeed, the Plaintiffs will be unable to prove that doctors even understood they were being offered alleged kickbacks, let alone that the kickbacks influenced their prescribing decisions. As a result, the Plaintiffs will be unable to prove that Novartis caused doctors knowingly to submit

false claims, that the alleged false claims were material to the Plaintiffs' payment decisions or that any prescriptions were written as a result of the purported kickbacks.

Likewise, the Plaintiffs will be unable to prove their federal and state unjust enrichment claims and their New York State statutory claims based on the same alleged conduct.

''Novartis additionally asserts the following defenses:

The Plaintiffs' claims fail because, at all times relevant hereto, Novartis complied with all applicable federal and state regulations.

The Plaintiffs' claims are barred, in whole or in part, to the extent that they seek to impose upon Novartis obligations that are inconsistent with, or in excess of, those imposed by existing law.

The Plaintiffs' claims fail because any and all actions taken by Novartis with respect to any of the alleged matters were taken in accordance with established industry practice. Such actions were also taken in good faith by Novartis.

The Plaintiffs' claims are barred, in whole or in part, because Novartis's alleged conduct falls within applicable statutory or regulatory exceptions or "safe harbors" in the AKS and any state law counterparts.

The Plaintiffs' claims fail because they are too remote and speculative to form the basis for relief. The Plaintiffs' claims are also barred, in whole or in part, because their alleged injuries were not proximately caused by the acts or omissions of Novartis but rather, if such injuries exist at all, were the result in whole or in part of intervening or supervening causes. In addition, the Plaintiffs' claims fail because they have not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of Novartis's alleged conduct.

The Plaintiffs' claims are barred, in whole or in part, by the doctrines of consent and/or ratification, as well as laches, estoppel and waiver. The Plaintiffs cannot obtain equitable relief against Novartis—such as its claims for unjust enrichment—to the extent the Plaintiffs have an

adequate remedy at law. Similarly, the Plaintiffs cannot receive double recovery for the same injury.

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Novartis respectfully reserves the right to raise any additional defenses not asserted herein of which it may become aware through pretrial discovery or disclosures, or through evidence introduced at trial.

V. JURY/NON-JURY AND DURATION OF TRIAL

This case is to be tried to a jury. The Plaintiffs anticipate that they will require between 20-25 trial days to put on their case-in-chief. Novartis anticipates that it will require between 15-20 trial days to put on its case-in-chief.

VI. MAGISTRATE JUDGE CONSENT

The parties have not agreed to trial of this case by a Magistrate Judge.

VII. STIPULATIONS OF FACT OR LAW

Attached as Exhibit A.

VIII. LIST OF TRIAL WITNESSES

Plaintiffs' Witness List is attached as Exhibit B-1.

Defendant's Witness List is attached as Exhibit B-2.

IX. DESIGNATIONS OF DEPOSITION TESTIMONY

Plaintiffs' deposition designations, along with Defendant's objections and counter-designations, are attached as Exhibit C-1.

Defendant's deposition designations, along with Plaintiffs' objections and counter-designations, are attached as Exhibit C-2.

X. EXHIBITS

Plaintiffs' Exhibit List, with Defendant's objections, is attached as Exhibit D-1.

Defendant's Exhibit List, with Plaintiffs' objections, is attached as Exhibit D-2.

The Parties' Joint Exhibit List is attached as Exhibit D-3.

XI. STATEMENT OF DAMAGES CLAIMED

Single damages to the United States with respect to both the First and Second Counts of its Amended Complaint in Intervention, asserting claims under the federal False Claims Act, as well as the total amount of wrongful payments alleged by its Third Count, asserting claims of unjust enrichment, are reflected in Exhibit E and total $402,932,925.78. This amount was calculated by summing, for each doctor who received a bribe from Novartis listed in Exhibit F, the government impact of payment for prescriptions for the Covered Drugs in the twelve months following receipt of a bribe from Novartis. The events through which Novartis provided these bribes are listed in Exhibit G. The government impact was calculated pursuant to the methodologies set forth in the expert reports of Professor Daniel McFadden.

Single damages to the State of New York with respect to its First and Second Claims for Relief of its Complaint in Intervention ("New York Complaint"), asserting claims under the New York False Claims Act, as well as its Fifth Claim for Relief, asserting claims under New York Executive Law § 63-c, and its Sixth Claim for Relief, asserting claims of unjust enrichment, total $12,487,893.46. This amount was calculated in the manner described above.

Single damages under the Relator's Third Amended Complaint total $40,247,666.91, allocated across its counts as follows:

- Count II, asserting claims under the Illinois Whistleblower Reward and Protect Action: $3,393,513.07.
- Count III, asserting claims under the California False Claims Act: $14,678,222.78.
- Count IV, asserting claims under the Florida False Claims Act: $2,760,768.14.
- Count V, asserting claims under the Texas False Claims Act: $2,545,356.92.
- Count VI, asserting claims under the Massachusetts False Claims Act: $229,619.06.

- Count VII, asserting claims under the Tennessee False Claims Act: $1,636,278.71.
- Count VIII, asserting claims under the Delaware False Claims and Reporting Act: $181,015.66.
- Count IX, asserting claims under the Nevada False Claims Act: $186,456.03.
- Count X, asserting claims under the Louisiana Medical Assistance Programs Integrity Law: $299,095.34.
- Count XI, asserting claims under the Hawaii False Claims Act: $189,956.82.
- Count XII, asserting claims under the D.C. Procurement Reform Amendment Act: $19,301.96.
- Count XIII, asserting claims under the Virginia Fraud Against Taxpayers Act: $750,677.87.
- Count XIV, asserting claims under the New Hampshire Health Care False Claims Law: $18,469.54.
- Count XVI, asserting claims under the Michigan Medicaid False Claims Act: $1,007,844.31.
- Count XVII, asserting claims under the New Mexico Medicaid False Claims Act: $71,019.27.
- Count XVIII, asserting claims under the Indiana False Claims and Whistleblower Protection Act: $319,994.68.
- Count XIX, asserting claims under the Connecticut False Claims Act: $399,889.93.
- Count XX, asserting claims under the Georgia False Medicaid Claims Act: $1,571,273.13.
- Count XXI, asserting claims under the Maryland False Claims Act: $1,695,787.97.
- Count XXII, asserting claims under the Minnesota False Claims Act: $85,813.38.
- Count XXIII, asserting claims under the Montana False Claims Act: $14,294.39.
- Count XXIV, asserting claims under the New Jersey False Claims Act: $6,813,311.43.
- Count XXVI, asserting claims under the Oklahoma Medicaid False Claims Act: $212,697.20.
- Count XXVII, asserting claims under the Rhode Island False Claims Act: $56,724.70.

- Count XVIII, asserting claims under the Colorado Medicaid False Claims Act: $82,028.98.
- Count XXIX, asserting claims under the Wisconsin Medicaid False Claims Act: $631,607.97.
- Count XXX, asserting claims under the Iowa False Claims Law: $232,119.36.
- Count XXXI, asserting claims under the Washington Medicaid Fraud Act: $164,528.31.

A table setting forth the breakdown of Medicaid damages per state is attached as Exhibit H. These amounts were calculated in the manner described above.

Novartis disputes Plaintiffs' Statement of Damages and contends Plaintiffs are entitled to no damages. In addition, Novartis objects to Plaintiffs' Statement of Damages on the bases that (1) it is untimely, as it reflects a new, previously undisclosed methodology of calculating damages; and (2) Plaintiffs have failed to make adequate accompanying disclosures to support this calculation of damages, in violation of Rule 26. Novartis hopes to be able to resolve this issue between the parties and does not seek the Court's intervention at this time.

Dated: New York, New York
April 8, 2019

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SO ORDERED.

Dated: New York, New York
_____, 2019

_____
HON. PAUL G. GARDEPHE
United States District Judge